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## **I. INTRODUCTION**

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. (“RBP”), RB Pharmaceuticals Limited (“RBP UK”), and MonoSol Rx, LLC (“MonoSol”) (collectively, “Plaintiffs”) respectfully submit this memorandum in opposition to Defendant BioDelivery Sciences International, Inc.’s (“BDSI’s”) motion to stay pending *inter partes* review.

## **II. NATURE AND STAGE OF PROCEEDINGS**

Plaintiffs commenced this action on October 29, 2013, asserting that BDSI’s proposed Bunavail™ product that is the subject of a New Drug Application (“NDA”) before the FDA, infringes U.S. Patent No. 8,475,832 (the “’832 Patent”). On December 13, 2013, BDSI moved to dismiss the complaint on purported standing and jurisdictional grounds. That motion is now fully briefed. On January 15, 2014, BDSI petitioned the United States Patent and Trademark Office (“PTO”) for *inter partes* review (“IPR”) of claims 15-19 of the ’832 Patent. On January 31, 2014, BDSI moved to stay this litigation pending the PTO decision whether to institute an IPR proceeding and during the IPR if instituted.

## **III. SUMMARY OF ARGUMENT**

This action should not be stayed pending a possible IPR of some claims of the ’832 Patent because, contrary to BDSI’s bare assertions, Plaintiffs will be substantially and unduly prejudiced by a stay, and, in addition, the IPR requested does not involve two of the three independent claims of the ’832 Patent, which will be subject to litigation in this Court in any event. More specifically, the essential facts are these: BDSI has a New Drug Application pending before the FDA, is eligible to receive FDA approval for its Bunavail™ product on June 7, 2014, and expects that product to compete directly with Plaintiffs’ commercial product, Suboxone® sublingual film, the leading treatment for opioid dependence. In its submissions to

this Court, BDSI has tried to portray the situation as one where BDSI's intentions and actions in regard to commercialization are entirely speculative. But BDSI's own press releases and securities filings clearly show otherwise. BDSI is taking, and telling the investing public (but not this Court) that it is taking, concrete steps to commercialize its product. For example, just two weeks ago, BDSI publicly announced that it had obtained a \$60 million investment and that "[p]roceeds from this financing are expected to be used" in part for:

***Execution of the sales, marketing and other commercialization and product supply chain activities to support the anticipated second half 2014 launch of BUNAVAIL™, BDSI's treatment for opioid dependence which is currently under review by the FDA with a June 7, 2014 PDUFA date, and that BDSI is actively preparing to commercialize on its own;***

*BioDelivery Sciences Closes \$60 Million Registered Direct Offering*, Feb. 13, 2014 (emphasis added), attached as Exhibit 1. Elsewhere, BDSI has publicly stated that it plans to launch Bunavail™ in the third quarter of 2014 and that it expects to garner up to \$250 million in sales. *BioDelivery Sciences Provides an Update of Anticipated 2014 Milestones*, Jan. 10, 2014, attached as Exhibit 2. Therefore, there can be no doubt that BDSI is planning to launch its product a few months from now and is raising money and very actively taking steps to do so. Accordingly, on that basis alone, it clearly makes sense to allow this case to go forward because any stay would unduly prejudice Plaintiffs.

Furthermore, BDSI's FDA approval eligibility date is almost two months earlier than the date, July 30, 2014, that the PTO is expected to decide whether to grant BDSI's IPR request.<sup>1</sup> And, if instituted, the IPR will not conclude until a year later, July 30, 2015 – almost one and half years from now. As BDSI would have it, Plaintiffs' infringement suit would be stayed even

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<sup>1</sup> BDSI is correct that the PTO has been instituting the majority of IPRs requested. But it is also true that often those institution decisions are on fewer than all grounds proffered by the Petitioner and that the PTO rejected BDSI's last two requests to institute IPRs against MonoSol pharmaceutical film technology patents.

if BDSI launches its product, as BDSI has publicly stated it is planning to do, in the third quarter of 2014. Additionally, contrary to BDSI's misleading and incorrect statement of the law, a PTO decision in the IPR will **not** be binding on this Court upon issuance, but only when either the time to appeal that decision has run or the case is finally decided on appeal. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1346 (Fed. Cir. 2013). An appeal to the Federal Circuit is likely to take an additional year, such as until sometime in the latter half of 2016 (and a certiorari petition to the Supreme Court even longer). The Court should decline BDSI's invitation to stay this action for some 2.5 years or more (through appeal) while BDSI prepares to launch and launches its Bunavail™ product that is meant to directly compete with Plaintiffs' Suboxone® film product. Under BDSI's approach, this case would be unjustifiably stayed even while BDSI was selling an infringing product for two years or more.

Additionally, the '832 Patent has three independent claims. However, as noted above, BDSI's IPR request only challenges one of those: independent claim 15 (and dependent claims 16–19) of the patent. As is typical of alleged infringers, it can be anticipated that BDSI will contend that it does not infringe the remaining claims of the patent. But that is no reason to stay this action as to those claims, particularly in light of the timeline discussed above (as to BDSI's fairly imminent FDA approval eligibility date, its aggressive launch preparation activity and the IPR/appeal timeline). Therefore, the fact that two of the three independent claims of the patent are not subject to the IPR request further strongly militates against BDSI's motion to stay the case as a whole. This is all the more true given the distinct differences in claim language between the claims. For example, the claims that are the subject of the IPR request recite certain bloods level parameters (Cmax) with respect to the active ingredients, while the claims that are not involved in the IPR request do not contain any such blood level limitations and instead

specifically recite certain “local pH” ranges in the mouth in regard to absorption of the active ingredients. Accordingly, for these reasons, as well it does not make sense for the entire case to be stayed. And again, this is particularly true given BDSI’s product launch timeline and the multi-year delay in addressing it that would be caused by a stay pending IPR and appeal. Therefore, Plaintiffs respectfully submit that the only appropriate course is not to stay the case, but to allow the litigation to go forward on all claims.

For these reasons and those discussed below, BDSI’s motion to stay should be denied.

#### **IV. STATEMENT OF FACTS**

##### **A. This Action, Plaintiffs’ Suboxone® Film Product, And The ’832 Patent**

This action arises from BDSI’s filing of an NDA under 21 U.S.C. § 355(b)(2) (the “505(b)(2) application”) with the United States Food and Drug Administration (“FDA”), seeking approval, before the expiration of Plaintiffs’ asserted patent, to manufacture and sell a competing pharmaceutical film drug product to Suboxone® film that contains the same active ingredients and is intended to treat the same medical indication (the treatment of addiction to opioids). (D.I. 1, Compl. ¶ 3.) BDSI intends to market its competing product under the name Bunavail™. *Id.*

Plaintiff RBP’s Suboxone® products have long been the leading treatment for opioid dependence. Suboxone® was first marketed in a tablet formulation. Seeking a new and improved formulation, RBP worked with Plaintiff MonoSol, a pioneering pharmaceutical film technology company, to develop a pharmaceutical film formulation, Suboxone® sublingual film, which is the subject of the patent-in-suit. *Id.* ¶ 13.

On August 30, 2010, the FDA approved Plaintiffs’ NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. (D.I. 1, ¶ 3.) The ’832 Patent, titled Sublingual and Buccal Film Compositions, is listed in the Orange Book as covering Suboxone® sublingual film. *Id.* ¶ 18. Plaintiff RBP also

owns NDA No. 20-733 for Suboxone® sublingual tablet. *Id.* ¶ 15. Suboxone® sublingual tablet contains the same active ingredients as Suboxone® sublingual film (buprenorphine hydrochloride and naloxone hydrochloride). *Id.* Suboxone® sublingual film incorporates a novel drug delivery system, *i.e.*, pharmaceutical film technology, to treat opioid dependence. *Id.* ¶ 2. Suboxone® sublingual film is a highly successful product, which according to BDSI itself enjoys over a billion dollars in U.S. sales per year. *Id.* ¶ 32.

### **B. BDSI's Active Steps To Bring Bunavail™ to Market**

In its 2012 annual report, BDSI indicated that it “remain[ed] on track to file the NDA for Bunavail™ with the U.S. Food and Drug Administration (FDA) in mid-summer 2013, putting BDSI in the position to introduce the next branded transmucosal buprenorphine/naloxone film into the marketplace for opioid dependence.” (D.I. 1, Compl. ¶ 32.) That BDSI plans to compete directly with Plaintiffs’ Suboxone® film product is further highlighted by the fact that BDSI’s “pivotal bioequivalence study of BUNAVAIL compared [it] to Suboxone tablets and [included] a safety study conducted in 249 subjects undergoing maintenance treatment for opioid dependence with Suboxone film or tablets who were converted to BUNAVAIL for 12 weeks.” *BioDelivery Sciences Announces Four BUNAVAIL Abstracts to be Presented at the 2014 American Society of Addiction Medicine Annual Conference*, Jan. 30, 2014, attached as Exhibit 3.

As to BDSI’s active preparations for an imminent launch, in a January 10, 2014 press release concerning anticipated 2014 milestones, BDSI, noting that the “review of the BUNAVAIL NDA is expected to be completed by June 7, 2014,” confirmed that BDSI:

**continues to develop the commercialization plans for the launch of BUNAVAIL** for the maintenance treatment of opioid dependence. As previously reported, the U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) **date of June 7, 2014 for**

**BUNAVAIL, which if approved is anticipated to launch late third quarter 2014. BDSI estimates annual peak U.S. sales of BUNAVAIL of up to \$250 million.**

“This year will potentially provide two of the most significant value driving milestones that our company has ever experienced,” said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. “We look forward to the results of our two Phase 3 studies for BEMA Buprenorphine for the treatment of chronic pain, which could potentially lead to an NDA submission late this year. **We are also extremely excited about the prospects of an NDA approval for BUNAVAIL this coming June with a launch shortly thereafter.**”

See Ex. 2 (emphasis added).

Even more recently, BDSI touted a \$60 million infusion, publicly declaring that the money was to be used, in part, for the “[e]xecution of the sales, marketing and other commercialization and product supply chain activities to support the anticipated second half 2014 launch of BUNAVAIL,” which BDSI states it is “*actively preparing to commercialize on its own.*” See Ex. 1 (emphasis added). BDSI’s February 7, 2014 prospectus supplement for investors further explains that such funds will be used, among other things, to:

**execute sales, key marketing and other commercialization activities to support the anticipated launch of BUNAVAIL™ if the product is approved by the FDA, ,which we are actively preparing to commercialize on our own, such as support advertising and promotion, sales force, recruitment, training and development, managed markets activities, post-approved clinical studies and manufacturing . . . .**

*BioDelivery Sciences Prospectus Supplement*, Feb. 7, 2014, SA-15, attached as Exhibit 4.

BDSI is doing just what it has told its investors and the public that it would do: actively prepare to commercialize Bunavail™. BDSI made a substantial investment in submitting an NDA for Bunavail™ to the FDA. It ran clinical trials involving upwards of 250 patients. It publicly told its investors – from whom it has raised tens of millions of dollars –that it is actively taking the full range of steps necessary to imminently launch Bunavail™, an event which BDSI regards as one of the two biggest milestones in the company’s history. At the same time, BDSI

has tried to avoid the imposition of a thirty-month stay of FDA approval<sup>2</sup> and to avoid this lawsuit by, first, filing a baseless motion to dismiss and, now, seeking to stay the case based on its recent IPR request.

### **C. BDSI's IPR Request And The IPR Timeline**

The following points are not in dispute:

- BDSI's petition for IPR only challenges claims 15–19 of the '832 Patent.<sup>3</sup> (D.I. 34, p. 3.)
- BDSI's IPR petition, therefore, does not challenge claims 1 through 14 of the '832 Patent, including independent claims 1 and 9. *Id.*
- The PTO will decide whether or not to institute BDSI's petition by July 30, 2014. (D.I. 34, p. 8.)
- If an IPR is instituted, the PTO's final decision on the IPR likely will not issue until July 30, 2015. That decision can then be appealed to the Federal Circuit. (*Id.*; 35 U.S.C. § 141(c).)
- While most IPR requests thus far have been granted, it is often the case that the PTO does not institute the IPR on all grounds proffered by the Petitioner. (D.I. 34-6, p. 3).
- The PTO rejected both previous IPR requests BDSI made as to MonoSol-related patents. IPR2013-00315 and IPR2013-00316.

Therefore: (1) the requested IPR will not involve two of the three independent claims of the '832 Patent; (2) the PTO's decision on whether to institute the IPR will not occur until almost a month after BDSI's eligible-for-approval date (June 7, 2014) for Bunavail™; and (3) a final decision by the PTO in an IPR, if instituted, will not come until approximately one year after

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<sup>2</sup> BDSI circumvented the provisions of the Hatch-Waxman and filed a 505(b)(2) application that relies on Suboxone® tablet NDA efficacy data, rather than relying on the Suboxone® film NDA and providing a Paragraph IV certification against the Orange Book-listed patents covering Suboxone® film.

<sup>3</sup> In challenging those claims in the context of an IPR proceeding, BDSI cannot address infringement issues and can only assert invalidity (obviousness or anticipation) based on prior art publications or patents, but on no other grounds.

BDSI intends to launch Bunavail™ in the third quarter of this year, and that decision can be appealed to the Federal Circuit. Accordingly, granting a stay of this case pending an IPR, if instituted, would mean staying this entire action even though only one of three independent claims of the patent would be subject to the IPR and preventing plaintiffs from litigating BDSI's infringement of the patent during what BDSI hopes and expects to be at least a one year period – from launch in the third quarter of this year until a decision by the PTO on July 30, 2015 – and likely at least a two year or more period – when whichever side loses the IPR appeals to the Federal Circuit (and possibly seeks certiorari to the Supreme Court).

## **V. ARGUMENT**

### **A. Legal Standards**

“The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion.” *Nken v. Holder*, 556 U.S. 418, 433–34 (2009). “The decision of whether to grant a stay rests within the sound discretion of the court as a product of its inherent power to manage its own docket so as to conserve judicial resources.” *Davol, Inc. v. Atrium Med. Corp.*, No. 1:12-CV-0958-GMS, 2013 U.S. Dist. LEXIS 84533, at \*3 (D. Del. June 17, 2013) (unpublished) (citing *Cost Bros. Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d. Cir. 1985)) (denying motion to stay pending IPR) (attached as Exhibit 5).

Courts consider three factors when deciding whether to grant a stay pending reexamination: (1) “whether a stay would unduly prejudice the nonmoving party”; (2) “whether a stay would simplify the issues and the trial of the case”; and (3) “the stage of the proceedings.” *Pentair Water Pool and Spa, Inc. v. Hayward Industries, Inc.*, No. 5:11-CV-459-D, 2014 U.S. Dist. LEXIS 12290, \*2 (E.D.N.C. Jan. 31, 2014) (unpublished) (citation omitted) (attached as Exhibit 6).

“The suppliant for a stay must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else.” *Williford v. Armstrong World Indus. Inc.*, 715 F.2d 124, 127 (4th Cir. 1983) (quoting *Landis v. North Am. Co.*, 299 U.S. 248, 255 (1936)).

**B. The Substantial And Undue Prejudice To Plaintiffs Weighs Decisively Against A Stay**

BDSI expects the FDA’s review of its NDA for Bunavail™ to be completed by June 7, 2014 and is planning to launch immediately upon approval. BDSI has repeatedly confirmed to the investing public that it is very actively preparing to commercialize Bunavail™, including raising tens of millions of dollars and taking all steps preparatory to the marketing of the product. BDSI expects Bunavail™ to compete directly with Plaintiffs’ Suboxone® film product and to gain up to \$250 million in sales.<sup>4</sup> Plaintiffs would clearly be substantially and unduly prejudiced if, while BDSI is undertaking these commercializing activities in preparation of an imminent launch of Bunavail™ and while BDSI is actually attempting to deprive Plaintiffs of sales and market share by selling Bunavail™, Plaintiffs are prevented from litigating their infringement claims against BDSI.<sup>5</sup>

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<sup>4</sup> In its opening papers, BDSI concedes that its Bunavail™ product “**will compete with Plaintiffs’ Suboxone Film product.**” (D.I. 34, p. 2) (emphasis added). Similarly, BDSI has stated that FDA approval will allow Bunavail™ to be “**the first buccal film dosage form containing buprenorphine for the treatment of opioid dependence that will compete with the market leader Suboxone . . .**” (D.I. 1, Compl. ¶ 33) (emphasis added). On August 1, 2013, BDSI’s Chief Executive Officer declared: “It is our intention to bring to market a product that we believe positions us to significantly participate in this \$1.5 billion and growing [opioid treatment] market.” (D.I. 1-2, Compl. Ex. B).

<sup>5</sup> Plaintiffs have not filed a motion for preliminary injunction and reserve the right to do so at any time. However, the absence of a pending motion for preliminary injunction does not undermine Plaintiffs’ prejudice arguments. *See Universal Electronics, Inc. v. Universal Remote Control, Inc.*, 943 F. Supp. 2d 1028, 1034 (C.D. Cal. 2013) (“The fact that Plaintiff did not seek a preliminary injunction does not mean that it would not suffer prejudicial harm from its competitor’s market activity during a lengthy delay in the case.”).

This prejudice and the unwarranted nature of such a stay is further compounded by the fact that the IPR only involves one of the three independent claims of the patent-in-suit and that, even if instituted, the IPR will not be resolved until July 30, 2015. An appeal to Federal Circuit from that decision would not come for about another year.

As BDSI would have it, because it has requested an IPR (on only one of three independent claims), it is somehow entitled to launch and sell its competing product for two years or more (if an IPR is instituted) without Plaintiffs being able to address BDSI's infringing activity through this lawsuit. BDSI's moving papers attempt to skirt the issue simply by denying that such substantial undue prejudice to Plaintiffs would exist. But the facts are clearly to the contrary and decisively weigh against a stay.

**1. If The Case Is Stayed, BDSI Will Obtain An Undue Competitive Advantage**

If this case is stayed, BDSI will obtain an undue competitive advantage to Plaintiffs' unjustified detriment. BDSI is clearly trying to position itself to be able to imminently launch its competitor product and to sell it for years while preventing Plaintiffs from pursuing relief from those infringing activities. Completely contrary to BDSI's non-credible assertions in its opening papers (*i.e.*, "there is no concrete indication as to whether or when BDSI will begin selling BUNAVAIL" (D.I. 34, p. 7)), BDSI's own publicly announced actions and repeated public statements unequivocally demonstrate a concrete indication of BDSI's intentions as to both.

Prejudice to the patentee is heightened when parties to litigation are direct competitors; in such cases, courts presume that a stay will prejudice the non-movant. *Otto Bock HealthCare LP v. Össur hf*, No. 8:13-CV-00891-CJC, D.I. No. 110, slip op. at 4 (C.D. Cal. Dec. 16, 2013) (unpublished) (citing *ADA Solutions, Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d 348, 351

(D. Mass. 2011)) (attached as Exhibit 7); *see also Ultratec*, 2013 U.S. Dist. LEXIS 162459, at \*11 (noting that “defendants have the burden of proof backwards;” they must show “that the stay will not prejudice plaintiffs and will not give defendants a tacit advantage”); *Avago Techs. Fiber IP (Singapore) PTE, Ltd. v. Iptronics, Inc.*, No. 10-CV-02863, 2011 U.S. Dist. LEXIS 82665, at \*16 (N.D. Cal. July 28, 2011) (unpublished) (“[I]nfringement among competitors can cause harm in the marketplace that is not compensable by readily calculable money damages. Staying a case while such harm is ongoing usually prejudices the patentee that seeks timely enforcement of its right to exclude.” (citation omitted) (citing *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1327–28 (Fed. Cir. 2008))) (attached as Exhibit 8). In *Ultratec*, the Court noted the prejudicial harm the plaintiffs would suffer as a result of the lengthy stay:

Inter partes review would allow defendants up to two years (six months for decision on whether to grant petition and 12 to 18 months for review) to gain market share and other advantages over plaintiffs while allegedly infringing plaintiffs’ patents. Plaintiffs and defendants are direct competitors in a small market. Thus, there is a greater likelihood that plaintiffs will lose significant market share to defendants.

2013 U.S. Dist. LEXIS 162459, at \*11–12; *see also Davol*, 2013 U.S. Dist. LEXIS 84533, at \*3 (“[T]here is a reasonable chance that delay in adjudicating the alleged infringement will have outsized consequences to the party asserting infringement has occurred, including the potential loss of market share and an erosion of goodwill.”).

The same is true here. There is no justification for the undue commercial advantage BDSI seeks to obtain through a stay, nor is there any compelling reason to deprive Plaintiffs of their ability to litigate their infringement claims against BDSI (a conclusion only further bolstered by the fact that the IPR request does not address two of the three independent claims of the patent).

## 2. Granting A Stay Will Cause Significant Delay In This Case

The PTO has not yet even decided whether to institute the proceeding requested by BDSI. Under the new IPR procedures, the PTO's Patent Trial and Appeal Board ("PTAB") must decide whether to grant review within six months of a petition being filed, and the PTO must then normally complete its review and issue a final determination within twelve months. *See* 35 U.S.C. §§ 314(b), 316(a)(11); 37 C.F.R. § 42.107. Thus, in some cases, from the point of filing of the petition, it could take eighteen months until adjudication of the proceeding. Here, it can at least be said that it is likely that, if instituted, the IPR would not be adjudicated until July 30, 2015—almost a year after BDSI has stated it will launch its Bunavail™ product.

Further, BDSI fails to mention the possibility of a subsequent Federal Circuit appeal (or appeals) and the additional delay it would cause. *See* 35 U.S.C. § 141(c). BDSI misleadingly and incorrectly states that the "PTO's invalidation of claims . . . is binding on Article III courts." (D.I. 34, p. 6) (citing *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013)). But a final decision by the PTAB is *not* in and of itself the final say on patent validity. The Director of the PTO does not issue a certificate confirming or canceling the claims subject to an IPR until the *later* of the time for appeal expiring or "any appeal has terminated." 35 U.S.C. § 318(b).<sup>6</sup> It typically takes about one year for an appeal to the Federal Circuit to be resolved (and then, of course, a party could seek a writ of certiorari from the Supreme Court). Therefore, as if a one year delay in litigation is not prejudicial while a competitor is selling a competing product, BDSI greatly misstates the period of time that the stay it seeks would likely impact this

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<sup>6</sup> The tortured history of the reexamination and appeal at issue in *Fresenius* shows just how long the appeals process can drag on and, in fact, complicate matters while the plaintiff waits for its day in court. *See Fresenius*, 721 F.3d at 1334–35 (explaining that the Board of Patent Appeals and Interferences affirmed the examiner's rejections in March 2010 and the Federal Circuit affirmed that rejection in May 2012).

litigation. In the event of institution of the IPR, a stay would likely delay litigation of this case by two years or more.

Courts have recently recognized that where PTO proceedings could be expected to last for nearly two years, grant of a stay was improper. *See Davol*, 2013 U.S. Dist. LEXIS 84533, at \*6–7 (“On the other hand, the status of the *inter partes* review is cause for some concern. . . . The PTO has not yet decided whether to grant Atrium’s petitions, and it is reasonable to assume that the process may continue into 2015. The court recognizes that such a delay risks unnecessarily impairing Davol’s patent rights, and finds that this sub-factor weighs against granting a stay.” (citation omitted)); *Ultratec, Inc. v. Sorenson Commc’ns, Inc.*, No. 3:13-CV-0346-BBC, 2013 U.S. Dist. LEXIS 162459, at \*11–12 (W.D. Wis. Nov. 14, 2013) (unpublished) (“Indeed, the length of time of inter partes review is prejudicial to plaintiffs, even though it is shorter than other Patent Office proceedings.”) (attached as Exhibit 9).<sup>7</sup>

Accordingly, BDSI’s conclusory assertions in support of its motion for a stay are just that: makeweight arguments that merely deny or ignore the substantial prejudice to Plaintiffs and the substantial delay that would be caused by granting its motion. Thus, BDSI asserts that Plaintiffs’ case would be “at most slightly delayed” and that there would be “no tactical disadvantage or prejudice to Plaintiffs.” (D.I. 34, p. 10.) However, as shown above, a stay would cause substantial delay and result in severe and unwarranted prejudice to Plaintiffs: the PTO’s decision on institution of the IPR will not be until about one month after the June 7 PDUFA date for Bunavail™, a decision in the IPR itself, if instituted, will likely not be issued

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<sup>7</sup> BDSI makes a half-hearted attempt to tout the “benefits” of an IPR for Plaintiffs, noting that claims 15–19 will be “twice-blessed” if they survive. (D.I. 34, pp. 10–11.) Plaintiffs respectfully suggest that the Court look with great skepticism on efforts by Defendant to persuade the Court that relief Defendant seeks against its competitors—attempting to foreclose Plaintiffs’ ability for two years or more to address Defendant’s infringing activities—is somehow actually in Plaintiffs’ best interests.

until July 30, 2015, and an appeal to the Federal Circuit would likely take another year (if not more, plus the potential of time consumed for seeking certiorari to the Supreme Court).

### **C. Grant Of A Stay Will Not Simplify The Issues In Question**

At this point, any alleged benefits of an IPR, or of a stay, are pure speculation. The PTO is not expected to determine whether to institute the IPR for another five months, *see* 35 U.S.C. § 314(b), and the scope of the review is indeterminate until the PTO makes its decision because the PTO may choose to review “all or some of the grounds of unpatentability asserted for each claim,” 37 C.F.R. § 42.108(a). It is often the case that even when an IPR is instituted, it is not on all grounds proffered. And, of course, the PTO may reject the petition altogether—just like it did with the last two IPRs BDSI requested in regard to MonoSol-related patents.<sup>8</sup>

Furthermore, as noted above, BDSI’s IPR request only challenges one (claim 15) of the three independent claims in the ’832 Patent. Accordingly, the IPR – even if instituted – will not address claims 1–14 (including independent claims 1 and 9) of the patent, and, as discussed above, the scope of the claims subject to the IPR request is quite different from those that are not, including the fact that the latter do not contain the blood level (Cmax) parameters of the former

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<sup>8</sup> BDSI cites statistics for the grant of petitions for IPR, but fails to note that just recently, the PTO rejected BDSI’s petition for IPR for two patents. IPR2013-00315 and IPR2013-00316. Moreover, many courts have rightly rejected the speculative statistics-based argument that the PTO would grant IPR. *See, e.g., Rensselaer Polytechnic Inst. v. Apple Inc.*, No. 1:13-CV-0633-DEP, 2014 U.S. Dist. LEXIS 5186, at \*21 (N.D.N.Y. Jan. 15, 2014) (unpublished) (“[I]n light of the novelty of the still relatively new IPR procedures, the court is left to speculate regarding the likelihood (or not) of whether a petition will be instituted . . .”) (attached as Exhibit 10); *RR Donnelley & Sons Co. v. Xerox Corp.*, No. 1:12-CV-6198, 2013 U.S. Dist. LEXIS 176620, at \*10 (N.D. Ill. Dec. 16, 2013) (unpublished) (“[T]he Court finds Xerox’s assumption that the PTO will grant its petitions based solely on statistics too speculative.”) (attached as Exhibit 11); *cf. Baseball Quick, LLC v. MLB Advanced Media, L.P.*, No. 1:11-CV-1735, 2013 U.S. Dist. LEXIS 73713, at \*4 (S.D.N.Y. May 23, 2013) (unpublished) (“The court . . . concludes that none of these statistics are of much use in resolving the present motion—the statistics provided by the Commissioner for Patents are simply too general to serve as a reliable indicator of the outcome of this particular reexamination given its own procedural and substantive characteristics.”) (attached as Exhibit 12).

and the former do not contain the “local pH” limitations of the latter. Nor, of course, will the IPR address any issue of infringement. Moreover, even as to the challenged claims, the only validity issues that can be addressed in an IPR proceeding are anticipation and obviousness based on prior art publications and patents. 35 U.S.C. § 311(b).

For all of these reasons and those discussed above in regard to the undue prejudice a stay would cause to Plaintiffs, this case should go forward not only as to claims 1–14 of the ’832 Patent but as to the remaining claims as well. The language of the claims and the nature of their limitations are different, and therefore will involve different issues of claim construction, infringement and validity. Therefore, the IPR, even if instituted, will leave many issues relating to the other claims unaddressed. Nevertheless, in terms of the underlying work, the subject matter of all the claims had a common genesis, arising from the same research and development efforts. Therefore, as a matter of judicial economy and fairness to Plaintiffs, it only makes sense for the case to move forward as to all claims. See *Ultratec*, 2013 U.S. Dist. LEXIS 162459, at \*10 (“The mere potential for overlap on the question of validity is not sufficient reason to grant stay in this matter.”). At the same time, BDSI should not be allowed to bootstrap the fact that there are some areas of overlap between the subject matter of the claims to further justify what is already a decisively flawed argument for stay; rather, in the circumstances presented here, given the undue prejudice and delay that Plaintiffs will suffer, no stay should be granted in any event, and any overlap between the claims only further militates in favor of denying a stay as to any aspect of the case.

Courts have denied motions to stay when the scope of IPRs is limited only to certain invalidity grounds under 35 U.S.C. §§ 102 and 103, leaving numerous other issues to be tried by the Court. For example, in *Otto Bock*, the Court held that where the petition for IPR only

encompassed certain of the asserted claims, a stay was not proper because the IPR would not resolve the case, including the unchallenged claims. *Otto Bock*, No. 8:13-CV-00891-CJC, slip op. at 3; *see also Davol*, 2013 U.S. Dist. LEXIS 84533, at \*17 (“[T]here are numerous issues to be tried regarding the ’334 and ’905 patents that cannot be addressed by Atrium’s petitions, including infringement, damages, validity under 35 U.S.C. § 112, and equitable defenses. . . . Given the numerous issues that will remain unresolved even if the PTO does grant review, this factor’s weight in the stay analysis is considerably reduced.” (internal quotation marks omitted)); *Ultratec*, 2013 U.S. Dist. LEXIS 162459, at \*11 (“Even if the Patent Office had granted the petitions, it is not clear that the inter partes review would address the issues that will be determinative in this case.”); *Automatic Mfg. Sys. v. Primera Tech., Inc.*, No. 6:12-CV-1727, 2013 U.S. Dist. LEXIS 67790, \*8 (M.D. Fl. May 13, 2013) (unpublished) (“Even if the USPTO decides to initiate a review, the law makes clear that the review itself is limited to anticipation and obviousness, which are only two of the many, many defenses to patent infringement.”) (attached as Exhibit 13); *IMAX Corp. v. In-Three, Inc.*, 385 F. Supp. 2d 1030, 1032–33 (C.D. Cal. 2005) (denying motion to stay pending reexamination and finding reexamination would not simplify the issues in litigation because “myriad issues in this case that will remain unresolved and unaddressed” even if the PTO eliminated all claims addressed in the reexamination).<sup>9</sup>

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<sup>9</sup> Many of the cases BDSI cites to support its argument that a stay would simplify or narrow the issues involve instances in which *every* patent claim at issue in the case had been subjected to reexamination or already rejected by the examiner during reexamination. *See Biogaia AB v. Nature’s Way Prods.*, No. 5:10-CV-449-FL, Pl.’s Mem. in Opp’n, D.I. 27, at 6 (E.D.N.C. Aug. 1, 2011) (identifying the two patents in suit and their claims in reexamination); *Cellectis S.A. v. Precision Biosciences, Inc.*, No. 5:08-CV-00119-H, Def.’s Mem. in Support of Mot. To Stay, D.I. 124, at 1 (E.D.N.C. Feb. 23, 2010) (arguing for stay because “the PTO has rejected all the claims at issue, including all the claims . . . that Cellectis has asserted against Precision”); *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, No. 5:07-CV-00389, Pl.’s Mem. in Support of Mot. To Stay, D.I. 26, at 1 (E.D.N.C. Nov. 30, 2007) (“[T]he patent-in-suit is in reexamination with the USPTO and . . . all claims have been rejected as unpatentable . . . .” (emphasis in original)); *Pragmatus AV, LLC v. Facebook, Inc.*, No. 5:11-CV-2168-EJD, 2011

BDSI concedes that its failure to challenge all claims at the PTO weakens its argument that a stay would narrow the issues in this case, and it backpedals by contending this is “not reason to prevent the stay with respect to the other claims in suit.” (D.I. 34, p. 15–16). As an initial matter, BDSI has the burden backwards—it is BDSI who carries the burden to show the stay will simplify the issues. *Cf. Ultratec*, 2013 U.S. Dist. LEXIS 162459, at \*11 (“The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion.”) (quoting *Nken v. Holder*, 556 U.S. 418, 433–34 (2009)). But, more importantly, this set of concerns speaks further to the delay and prejudice that will be imposed on Plaintiffs as a result of BDSI’s stay strategy. BDSI evidently envisions a scenario where not only are Plaintiffs prevented from litigating BDSI’s infringement for a period of two years or more while BDSI seeks to deprive Plaintiffs of sales and market share, but Plaintiffs will then be subjected to what could be a further delay of years more of litigation in this court and on appeal as to the claim construction, infringement, and validity of the claims not subject to the IPR (even if the IPR decision, or the appeal therefrom, went in favor of BDSI).

**D. The Stage And History Of This Litigation Do Not Favor A Stay**

It is true that this case is in its early stages, and it would even be true, if less so, if BDSI had not delayed the progress of the case by filing a baseless motion to dismiss the complaint (which is now fully briefed). However, for purposes of evaluating BDSI’s stay motion, Plaintiffs respectfully submit to the Court that the governing factor here is not that the case is at an early stage, but that BDSI cannot meet its heavy burden of showing that it is entitled to a stay in the circumstances presented here. If the stay is granted, Plaintiffs will suffer substantial undue prejudice and be placed at an unjustified competitive disadvantage because: (1) BDSI is

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U.S. Dist. LEXIS 117147, at \*8 (N.D. Cal. Oct. 11, 2011) (finding request for reexamination of “all claims at issue in this litigation” weighed in favor of a stay).

aggressively pursuing commercialization of, and expects to imminently launch, a product that is meant to directly compete with Plaintiffs'; (2) an IPR-based stay will (if the IPR is instituted) likely have duration of two years or more; and (3) most of the independent claims of the patent are not involved in the IPR request. BDSI has fallen woefully short of meeting its burden.

## **VI. CONCLUSION**

For the foregoing reasons, Plaintiffs respectfully request that the Court deny BDSI's Motion to Stay Pending *Inter Partes* Review in its entirety.

This the 24<sup>th</sup> day of February, 2014.

/s/ Robert D. Mason, Jr.

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